

Remarks

A restriction requirement under 35 U.S.C. §§121 and 372 was set forth in the Official Action dated June 20, 2007 in the above-identified patent application.

At the outset, it is noted that a shortened statutory response period of one (1) month was set forth in the June 20, 2007 Official Action. This response is being filed within the initial one (1) month response period.

As another preliminary matter, Applicants note that the Examiner has indicated that submission of SEQ ID NOS: for the elected genes will expedite prosecution. Each of the sequences encompassed by the amended claim is present in the public domain as indicated in the specification at page 23, third full paragraph. As recently held by the Federal Circuit, there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure...Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. See Falkner v. Inglis, 448 F.3d 1357, 1366 (Fed. Cir. 2006). Attached hereto is a print out of the information relating to the adenine phosphoribosyltransferase which is readily obtainable when searching the web using the Unigene identifiers provided in Table S6. Thus, the skilled person is clearly apprised of the subject matter encompassed by the present claims. Applicants also submit that inasmuch as the specification lacks recitations of 10 contiguous nucleotide bases or 4 contiguous amino acids, the application fully complies with the requirements of 37 C.F.R. §1.821-1.825.

It is the Examiner's position that claims 1-2, 5-20, and 22-37 in the present application are drawn to two (2) patentably distinct inventions which are as follows:

- Group I: Claims 2, 5-11, 13-15, 17-20, 22, 24-27, 29-31, and 33-37, drawn to a method for determining the prognosis of a patient based on the polynucleotide levels of genes from a prognostic set and a kit for performing said method, a method of producing a nucleic acid expression profile for a breast tumor sample comprising identifying the expression levels of a prognostic set of genes, and a method for identifying a set of genes that are differentially expressed at the polynucleotide level within a group of tumors.
- Group II: Claims 2, 5-11, 13-14, 17-20, 24-27, 29, 31, and 33-37, drawn to a method for determining the prognosis of a patient based on the polypeptide levels of genes from a prognostic set and a kit for performing said method, a method of producing a protein expression profile for a breast tumor sample comprising identifying the expression levels of a prognostic set of genes at the polypeptide level, and a method for identifying a set of genes that are differentially expressed at the polypeptide level within a group of tumors.

The Examiner further contends that each prognostic set represents a separate invention and the Examiner has required Applicants to elect a single prognostic set of genes for examination on the merits.

The Examiner has also identified claims 1, 12, 16, 23, 28, and 32 as linking claims. In accordance with §809 of the M.P.E.P., "[t]he linking claims must be examined with, and thus are considered part of, the invention elected. When all claims directed to the elected invention are allowable, should any linking claim be allowable, the restriction requirement between the linked inventions must be withdrawn. Any claim(s) directed to the nonelected invention(s), previously withdrawn from consideration, which depends from or requires all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability."

Applicants respectfully disagree with the Examiner's

restriction requirement and submit that a withdrawal of the instant restriction requirement is in order for the following reasons.

During the international stage of this application the PCT Examiner did not make a lack of unity finding and considered all of the claims to be directed to a single invention. Plainly, the instant restriction requirement fails to comply with the established United States Patent and Trademark Office practice of following the international rules regarding unity of invention in the prosecution of applications filed under §371. While the Examiner purports to employ the general inventive concept practice under PCT Rule 13.1, it is wholly unclear how the Examiner could conclude that the instant application has two (2) Groups of inventions, when the PCT Examiner, employing the same rules, determined that identical claims in the international application have complete unity of invention. Accordingly, Applicants respectfully request the instant restriction requirement be withdrawn and all of the claims be examined on their merits.

In addition, Applicants respectfully submit that the restriction requirement set forth above is improper for failure to comply with the relevant provisions of the M.P.E.P. pertaining to unity of invention determinations. As stated in §1893.03(d) of the M.P.E.P.:

Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 U.S.C. §371.

The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application.

The basic principle is that an application should relate to only one invention or, if there is more

than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.

The Examiner contends that the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1, because, under PCT Rule 13.2, they lack the same corresponding special technical features. It is the Examiner's position that the nucleic acid expression profile and a protein expression profile do not have a common property or activity. Furthermore, the Examiner states that under unity of invention between different categories of inventions, unity of invention will only be found to exist if specific combinations of inventions are present and gives examples where the claims will be considered to have unity of invention.

Applicants disagree with the Examiner's position and submit that the presently amended application contains a single expression profile and a method for determining the prognosis using a single prognostic set. Applicants submit that the different categories constitute "(4) A process and an apparatus or means specifically designed for carrying out the said process," and therefore, should be considered to have unity of invention.

The Examiner also contends that the products themselves (i.e., polynucleotides and polypeptides) do not share significant structural elements to the extent that each member could be substituted, one for the other, with the

expectation that the same intended result would be achieved.

Applicants respectfully disagree. Notably, under a proper consideration of unity of invention (as opposed to restriction practice), there is no rationale for separating out claims to a polypeptide, and a polynucleotide encoding it. Applicants respectfully submit that the novel and inventive prognostic gene set represents a link between the groups of claims, and further constitutes a single inventive concept as required under PCT Rule 13.1. Thus, it cannot be reasonable construed that the inventions are independent and distinct.

Additionally, according to the M.P.E.P. §803, there are two criteria for restriction between inventions which are alleged to be patentably distinct: 1) the invention must be independent or distinct as claimed, and 2) there would be a serious burden on the Examiner if restriction is not required. Despite the Examiner's assertion to the contrary, it is readily apparent from an objective reading of the inventions of Groups I and II that both groups are related since the inventions have a similar result (i.e., determining the prognosis of a patient with breast cancer). In other words, both groups are one in the same since both are useful for determining the prognosis of a breast cancer patient by utilizing a prognostic set of genes differentially expressed in tumors and, therefore, do not comprise separate and distinct inventions.

Applicants also respectfully submit that the examination of Groups I and II together cannot be reasonably regarded as imposing a serious search burden on the Examiner. Indeed, each of the groups is directed to determining the prognosis of a patient based on genes from a specified prognostic gene set. The Examiner's workload would not be unduly increased by searching the invention as presently claimed since polynucleotides and polypeptides have a disclosed relationship. In light of the fact that an

equivalent search for methods for determining the prognosis of a patient with breast cancer is required for both groups, Applicants submit that the Examiner's search burden would not be unduly increased by searching the groups together since they involve the same five (5) genes. Art relating to the polynucleotides would provide similar information on the polypeptides and vice-versa.

For all of the foregoing reasons, Applicants respectfully request withdrawal of the present restriction requirement.

In order to be fully responsive to the instant restriction requirement, Applicants hereby elect, with traverse, Group I, namely claims 2, 5-11, 13-15, 17-20, 22, 24-27, 29-31, and 33-37, drawn to a method for determining the prognosis of a patient based on the polynucleotide levels of genes from a prognostic set and a kit for performing said method, a method of producing a nucleic acid expression profile for a breast tumor sample comprising identifying the expression levels of a prognostic set of genes, and a method for identifying a set of genes that are differentially expressed at the polynucleotide level within a group of tumors. Applicants also elect the prognostic set which includes the first five genes of Table S6, namely, adenine phosphoribosyltransferase, MCM4 minichromosome maintainance deficient 4 (*S. cervisiae*), exonuclease 1, Metallothionein 1H-like protein, and clone IMAGE: 5270727.

Applicant's elections in response to the present restriction and election of species requirements are without prejudice to their right to file one or more continuing applications, as provided in 35 U.S.C. §120, on the subject matter of any claims finally held withdrawn from consideration in this application.

Early and favorable action on the merits of this application is respectfully solicited.

Respectfully submitted,
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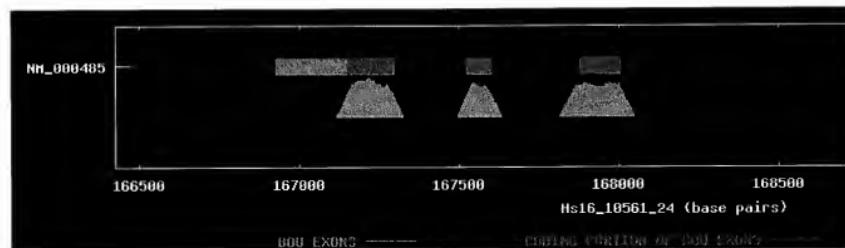
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Enclosure: Unigene print out for Hs.28914

HUMMUS: BOU -> Genome Mappings

UniGene cluster: UniGene Cluster Hs.28914
Description: **adenine phosphoribosyltransferase**
Best-Of-UniGene (BOU) **NM_000485**
Sequence
Genomic Coordinates **Bases 166426 to 169924 of contig**
Displayed: **Hs16_10561_24**
BOU Orientation Along Contig: **RIGHT-TO-LEFT with respect to contig**
Link to JPEG of genomic mapping **Hs.28914.jpeg**



This page provides information on exon-intron structure and mouse-human homologies of mRNAs and ESTs that are the Best-Of-UniGene (BOU) representatives of individual NCBI UniGene clusters. The exon-intron mapping of the BOU sequence itself is in blue and green. If annotated, coding portions of the BOU sequence are shaded blue. The remainder of the BOU is shaded green. Immediately below the BOU are HUMMUS-defined stretches of sequences highly conserved between mouse and human. The height of each bar is reflective of the % identity over a 50 base-pair window centered at a given base.